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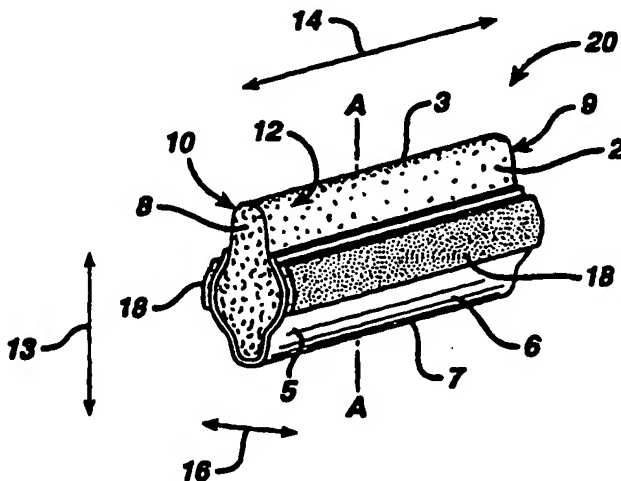
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(54) Title: **BODY-ATTACHABLE INTERLABIAL ARTICLES AND METHODS FOR MAKING THE SAME**

(57) Abstract

The present invention relates to an absorbent interlabial article containing attachment means on its body-facing surface, to allow the article to be releasably attached directly to a user's body. The interlabial article stays in place and is not inadvertently dislodged, while remaining atraumatic to wear and remove.



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BODY-ATTACHABLE INTERLABIAL ARTICLES AND METHODS FOR MAKING THE SAME

5 FIELD OF THE INVENTION

The present invention relates to absorbent sanitary protection articles that are sized and configured to fit predominantly between a woman's labia minora and/or majora and methods of making such articles.

10

BACKGROUND OF THE INVENTION

Sanitary protection articles can generally be placed into three categories: external pads that are positioned against the perineum and attached either to a user's undergarment or directly to a user's body; interlabial articles that are worn between and near the labia
15 minora and majora; and internal articles such as tampons and collection devices that are worn within the vaginal canal.

A large segment of menstruating women choose not to wear internal articles and therefore rely mainly on external pads, and more specifically on interlabial articles. External pads typically have large dimensions since they capture fluid after the fluid has
20 exited the vagina, having potentially traveled in multiple directions along or outward from the body. After external pads capture fluids, the possibility of fluid leakage is increased by distortion resulting from both the body's movement against the pad, and the undergarments, to which all commercial pads are attached, pulling the pad away from the body.

25 In an effort to reduce the failure rate of garment attached external pads, products have been invented to be attached directly to the body, see for example US Patent Number 5,658,270. However, such body adhering pads must be attached to the body along substantial portions of their body-contacting surface, to efficiently capture fluid. Interlabial articles, which are well known in the art, capture fluid closer to the site of
30 discharge than do external pads and yet do not reside within the vaginal canal, such as a tampon does. Residing between the labia, they are much smaller and discreet than pads. A recent example of an interlabial invention is disclosed in US Patent Number 5,484,429, which describes an article comprising a fluid pick-up module, wicking fibers and a capacity module. Other inventions, e.g., US patent Numbers 5,074,855 and 5,336,208,
35 describe devices that are designed to fit between the labia minora and the vestibule to seal and occlude the urethral meatus, for controlling female urinary incontinence. However,

such devices are intended to prevent the exit of urine and not to absorb it, and other bodily fluids such as menstrual discharge.

Interlabial articles until now have depended either on friction, close fit or a garment-attaching ancillary device to enable them to be positioned to absorb liquid discharges from the body and to maintain their position during use. Friction or fit separately, or in combination, has not proved to be reliable means for retaining these articles. Attachment by ancillary devices to the undergarment encourages the interlabial article to shift and pull away from the labia during use, similar to that experienced with external pads, thereby leading to the potential of leakage and irritation.

Thus, there exists a need for an interlabial article that stays in place, is not inadvertently dislodged, and is atraumatic to wear and to remove. These requirements are the broad objectives of this invention.

SUMMARY OF THE INVENTION

In accordance with one embodiment of the present invention, there has now been provided an absorbent article sized and configured to fit predominantly between a user's labia, comprising: an absorbent structure, having a proximal part and a distal part, comprising body-facing and opposite-facing outwardly disposed surfaces respectively; and adhesive located on at least a portion of the body-facing outwardly disposed surface, for releasably attaching the article to the user's body.

In accordance with a second embodiment of the present invention, there has now been provided an absorbent article sized and configured to fit predominantly between a user's labia comprising: an absorbent structure, having a liquid permeable outer surface; at least one lateral extension comprised of a liquid impermeable material, outwardly deployed from a distal edge, the lateral extension having a body-facing surface and an opposite-facing surface; and adhesive located on at least one of the liquid permeable outer surface and the lateral extension body-facing surface, for releasably attaching the article to the user's body.

In addition to the unique absorbent articles above, the present invention also provides two preferred methods of making such articles. The first method comprises the following steps:

- a) providing a web of absorbent material, having a central longitudinal axis;
- b) covering at least part of said web with a liquid permeable material;

- c) folding the web on itself along its central longitudinal axis, thereby forming a folded edge and juxtaposed sections;
 - d) folding the juxtaposed sections of the web outward from and coplanar with each other, along a line distal to said folded edge, thereby forming a web structure having a projection and base sections, wherein the distance between the line and the folded edge defines a projection height;
 - e) providing a liquid impermeable material, having a central longitudinal axis;
 - f) folding the liquid impermeable material on itself along its central longitudinal axis, thereby forming a folded edge and juxtaposed sections;
 - g) folding the juxtaposed sections of the liquid impermeable material outward from and coplanar with each other along a line distal to said folded edge, thereby forming a liquid impermeable structure having a projection and base sections, wherein the distance between the fold line and the folded edge defines a projection height;
 - h) aligning and attaching the web base sections to the liquid impermeable base sections, wherein the web projection and the liquid impermeable projection are outwardly disposed in opposite directions, thereby forming a absorbent structure; and
 - i) separating the absorbent structure into a plurality of absorbent interlabial articles.
- The second method comprises the following steps:
- a) providing a web of absorbent material, having a central longitudinal axis;
 - b) folding the web on itself along said axis, thereby forming a folded edge and a second edge comprising juxtaposed web ends;
 - c) providing a liquid impermeable material;
 - d) wrapping the liquid impermeable material around the juxtaposed web ends, wherein the wrapped liquid impermeable material has a outwardly disposed surface, thereby forming an absorbent structure; and
- separating the absorbent structure into a plurality of individual absorbent interlabial articles.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of one embodiment of the present invention.

FIGURES 2-6 illustrate multiple profiles of the absorbent interlabial article's proximal section provided by the present invention, including alternative adhesive patterns.

5 FIGURES 7-10 illustrate multiple cross sections of absorbent interlabial articles provided by the present invention.

FIGURES 11-13 are perspective views of multiple embodiments having differing proximal part profiles.

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FIGURE 14 is a cross sectional view of an embodiment of the present invention having optional liquid accepting, transporting and storing absorbent components.

FIGURE 15 depicts an absorbent interlabial article having two lateral extensions, and adhesive regions on both the lateral extensions and a proximal part.

15

FIGURE 16 illustrates an embodiment of the present invention having large lateral extensions, allowing portions of the lateral extensions to wrap around a crotch section of a user's undergarments.

20

FIGURES 17a-17f illustrate steps of a first method for making a body-attachable interlabial article.

FIGURES 18a-18b illustrate steps of a second method for making a body-attachable interlabial article.

25

DETAILED DESCRIPTION OF THE INVENTION

The absorbent interlabial article of the present invention is designed to stay in place, without being inadvertently dislodged during use, be comfortable and not irritating to wear, and be easily and painlessly removed to be discarded when it is no longer needed, or when it needs to be changed. This invention effectively and efficiently absorbs liquid discharges such as those that emanate from the following: the vagina and cervix before, during and between menstrual periods, the urethral meatus and from sweat glands.

30

There is adhesive means incorporated into the present invention to aid in the articles secured placement to the body during use. The adhesive means are such to provide safe, non-irritating adherence to that part of the body, to retain the device during use and to permit its safe and atraumatic removal after use.

5 To discuss the design, placement and use of the device it will be helpful to describe female external genital organs and their peripheral anatomical structures where the device is to be used. The perineum is the entire external genital area rearward from the anus forward to the mons pubis and laterally from the inside of one thigh to the other thigh, the mons pubis being a mound of fatty tissue, covered with pubic hair, that overlays
10 the pubic bone. The vulva, a subsection of the perineum that encompasses the external female genitalia, includes the labia majora, which are two fatty mounds of skin covered with pubic hair that surround or cup the external genitalia. The labia majora, in turn, have inner labial surfaces and outer labial surfaces. The clitoris forms part of the anterior confluence, towards the mons pubis of the labia majora. The posterior fourchette
15 (posterior labial commissure) forms the posterior confluence, towards the anus, of the labia majora. Anatomical openings from which liquid discharges emanate, starting from the anterior portion of the perineum rearward, are: the urethral opening through which the urethra empties urine from the body; the vaginal opening, from which vaginal discharges such as menses and other vaginal secretions empty and various sweat glands.
20 The labia minora are soft flaps of tissue, within the labia majora, that surround the vaginal opening and clitoris. The vestibule is an area surrounding the vaginal opening and vulva.

The article can be attached to pubic hair covered parts of the perineum, such as the mons pubis and the vulva. Alternatively, the article can be attached to relatively hairless parts, such as the inner surfaces of the labia majora, the labia minora, and the inward
25 surfaces of the thighs and the cleft between the thighs and the perineum. Multiple areas of body attachment are also provided by the present invention.

The absorbent interlabial article of the present invention comprises a proximal part, which faces the body and penetrates the labia; a distal part, which faces opposite the body; an anterior end, that faces, but preferably does not contact the clitoris in use; a
30 posterior end, that faces, but preferably does not contact the posterior fourchette; a height that determines the degree of interlabial penetration; a length that provides coverage of the vaginal opening and the urethral meatus; and a width that provides good fit for the space between the labia.

Although, the article is intended to primarily fit between the labia, the article preferably contains lateral extensions that can have both interlabial and extralabial residence.

The following is a detailed description of the invention depicted in the Figures.

5 Figure 1 shows a perspective view of a first embodiment of an absorbent article 20 of this invention, wherein this embodiment may optionally have a liquid impermeable barrier 5 to help prevent liquid from escaping absorbent article 20 onto the user's clothing. Absorbent article 20 contains absorbent material and comprises: a proximal part 2 that has an outer edge 3 which furthest penetrates the space at least between the labia majora;

10 a distal part 6 that has an outer edge 7 and is opposite proximal part 2; an anterior end 8 that faces but preferably does not contact the clitoris in use; a posterior end 9 that faces but preferably does not contact the posterior fourchette, two opposite lateral faces 10, 12, located between outer edges 3 and 7, a height 13 that determines the degree of interlabial penetration, a length 14 that provides coverage of the vaginal opening and/or the urethral

15 meatus, and a width 16 that provides good fit within space between the labia and provides good contact with at least the distal parts of the labia majora. Importantly, absorbent article 20 also comprises an adhesive 18, preferably a body-adhering adhesive, for attaching absorbent article 20 to the body, here the labia majora and/or the vulva. Line A-A is also depicted in Figure 1 as a line for cross section to be referred to in Figures 7-10

20 forthcoming.

Height 13 should be sufficient to permit penetration of the space between the labia by absorbent article 20 to capture and absorb liquid discharges from the body, without placing excessive pressure on the labia minora and the vestibule. Height 13, for adequate penetration, measured from the floor of the vulva outside the vulva, may be in the range

25 from about 3 mm to about 6.5 mm, and preferably from about 6.5 mm to about 9.5 mm, depending on the anatomical dimensions of the user. Height 13 may also be greater than about 10 mm, thereby yielding a height that may be greater than that required for adequate and comfortable penetration of the space between the labia, if the excess height is permitted to be exposed outside the vulva. Such excess height is also useful as an aid

30 for the user to grasp to insert and remove absorbent article 20. Height 13 need not be unvarying. It may, for example, be preferably higher at posterior end 9, to capture vaginal discharges, than at anterior end 8, where it preferred that it does not encroach on the sensitive clitoris. It may also be the same or not the same height at anterior and

posterior ends 8, 9, respectively, and higher or lower, therebetween, than either anterior end 8 or posterior end 9.

Length 14 may vary in the range from about 6 mm to about 75 mm, preferably from about 12 mm to about 45 mm, and most preferably from about 20 mm to about 30 mm, depending on such factors as whether absorbent article 20 is intended to cover the vaginal orifice, the urethral meatus or both, without irritatingly contacting the clitoris and posterior fourchette, and the anatomical dimensions of the user.

Length 14 may be the same as or different, in being greater or smaller, for proximal part 2 and distal part 6. The dimension along the perimeter of the proximal part 2 will dictate the amount of coverage the article will provide for a given user. Some consumers may have needs for the article to cover both the vaginal opening and the urethral meatus, for management of cervical discharges and urine. Alternatively, an interlabial article with a proximal section having a reduced perimeter dimension, would allow for the article to remain in place for collecting cervical discharge, while providing unrestricted urination.

Width 16 may range from about 1.5 mm to as much as about 25 mm, but preferably from about 3 mm to not greater than about 12.5 mm, depending on the anatomical dimensions of the user and amount of liquid discharge it is meant to capture, and should be sufficient to fit comfortably and closely within the space between the labia to efficiently capture liquid discharges. Width 16 need not be unvarying. However it may, for example, be preferably greater or smaller at proximal part 2 than at distal part 6.

Unless otherwise noted, the number designations used in Figure 1 are understood to be the same as used throughout the remainder of the specification.

Figures 2-6 show examples, without being restricted to same, of article side views 25, 30, 35, 40, 45, respectively, that reflect the foregoing discussion on length 14 and height 13, where proximal part 2, distal part 6, anterior end 8, posterior end 9 and one lateral face 10 are identically labeled as in Figure 1.

Figures 2-6 also show examples of alternative patterns and placement of adhesive 18 on the lateral face 10, which is shown. Adhesive 18 may be applied in one or several places on absorbent structure 20 in the form of a continuous coating, a discontinuous coating, contiguous segments of a coating, separated segments of a coating, a patterned coating a fibrous coating and combinations thereof. Coating patterns may be such as dots, dashes, circles, symmetric, asymmetric and abstract designs and combinations thereof.

Figures 7-10 depict articles 50, 55, 60, 65, having various cross-sectional geometries. Such cross-sectional profiles may represent anterior end 8, posterior end 9 and any cross-section therebetween, such as taken along line A-A of Figure 1, of the various embodiments provided by the present invention, including those depicted in the remaining figures.

It is obvious to one skilled in the art that combinations of profiles of width and length may be employed to give optimum protection with comfort and retention of the device between the labia. The profile of proximal part 2 may differ to provide more or less contact with the female genitalia, to achieve a balance between comfort and good contact and fit for efficient capture of liquid. Figures 11 and 12 show perspective views of articles 70 and 75 having examples of such profiles, where grooves 22 on the proximal part 2 have the effect of limiting contact with the female genitalia, while providing good liquid capturing ability, and preventing the liquid from bypassing the absorbent article. Figure 13 shows an absorbent article 80, having a flat proximal part 2 in order to provide more fluid accepting surface area, especially at the posterior end 9, intended to be positioned proximal a user's vaginal orifice, without creating uncomfortable bulk at the anterior end 8, intended to be positioned proximal a user's urethral meatus.

Figure 14 depicts an absorbent article 85 in a cross sectional view, illustrating liquid accepting, transporting and storing absorbent components that may exist. Absorbent article 85 has a body-facing and contacting surface 26 and an opposite-facing surface 54. Absorbent article 85 herein comprises, sequentially, an absorbent core 34 and optionally the following: a liquid permeable cover 32; a transfer layer 28, to move liquid directly across to absorbent core 34; a wicking means 36 to move liquid downward from a proximal part 38 toward a distal part 42; and a liquid barrier 44. Also shown, is an adhesive means 46, for attaching the article directly to a user's body. A release paper (not shown) to protect the adhesive 46 before the product is used can optionally be employed.

Wicking means 36 may be made of materials having good wicking characteristics such as tissue, vertically oriented fibrous tow constructions, sphagnum moss and certain synthetic fiber webs such as polypropylene that have been treated by any number of means to make them hydrophilic and having the appropriate density and/or wicking enhancing structure to promote wicking away from the user's body and throughout the

Figure 15 depicts an absorbent article of the present invention with two lateral extensions. Absorbent article 100 is shown with adhesive regions 110 and 111 located on both a proximal part 102 and the lateral extensions 104. Adhesive regions could also be

limited to either the proximal part or the lateral extensions. Optional finger-grasping member 103 is also shown. Figure 15 illustrates a single structure that can provide both liquid absorbency, and a barrier to fluid leakage. One method of forming such a single structure is by molding the article out of a foam material, and then manipulating the material and / or molding process, such as by varying heat and / or pressure, to form both open celled and closed celled surfaces.

The absorbent article of the present invention preferably has at least one lateral extension, which can extend from between the labia to outside the labia (extralabial). Preferably the article contains two lateral extensions outwardly deployed from a first and second distal edge. The lateral extensions can also contain adhesive on portions of an outwardly disposed surface directed towards a user's body. Adhesives and their techniques of application, that are useful for extralabial surfaces, such as the mons pubis, outer labial surfaces and insides of the thighs are described in commonly assigned US 5,658,270, herein incorporated by reference.

The lateral extensions are preferably constructed of material, which is inherently extensible, or can be manipulated to provide extensibility, allowing the lateral extensions to adhere to the inner thighs, and maintain the adherence during normal activity. The materials can be made extensible by performing a mechanical operation, such as pleating, corrugating, or ring rolling. In addition, the material can be perforated or slit. The perforations or slits can vary in geometry and size, thereby providing extensibility in multiple directions if needed. The materials can also be inherently stretchable, such as polyethylene blended films available from Exxon, particularly film EXX-7. A more detailed disclosure of extensible articles, and methods of making such, is contained in US Patent Number 5,824,004, herein incorporated by reference.

Also contemplated within the present invention is for the lateral extensions to be sized and configured for wrapping around, and attaching to, a crotch portion of a user's undergarment. This embodiment, as shown in Figure 16, provides adhesive located on an outwardly disposed surface of the lateral extensions directed away from the body, in order for the adhesive to adhere to the outer surface of the user's undergarment. Absorbent article 90 is shown with lateral extensions 91 wrapped around a crotch portion 95 of an undergarment. There are adhesive regions 93 located on proximal part 94, as well as adhesive regions 92 located on the lateral extensions 91.

Figures 17a-17f illustrate steps included in a preferred method of making a body-adhering absorbent interlabial article as provided by the present invention. Figure 17a

depicts a section of an absorbent web 200, with optional fluid permeable cover material 201, and optional adhesive means 202 to provide stability to a web projection formed by folding the web on itself. The absorbent web 200 is folded on itself along the web central axis B-B, as shown in Figure 17a, to form a web structure 210 as shown in Figure 17b, having a web projection 203, and web base sections 204. Similar folding steps are then followed with a liquid impermeable material, wherein the liquid impermeable material is preferably gas permeable, acting as a barrier to prevent fluid from staining the user's body or undergarments. Figure 17c shows a section of a liquid impermeable liquid impermeable material 300, with optional adhesive means 302 to provide stability to a liquid impermeable projection formed by folding the liquid impermeable material on itself. The liquid impermeable material 300 is folded on itself along the liquid impermeable material central axis C-C, as shown in Figure 17c, to form a liquid impermeable structure 310 as shown in Figure 17d, having a liquid impermeable projection 303, and liquid impermeable base sections 304. The web structure 210 and the liquid impermeable structure 310 are then attached to one another. Figure 17e depicts the web structure 210 and the liquid impermeable structure 310, co-extensively aligned, and attached, wherein the web projection 203 and the liquid impermeable projection 303 are outwardly deployed in opposite directions to one another. Optionally, body-adhering adhesive can be applied to a portion of the web structure.

Figure 17f illustrates a finished body-adhering absorbent interlabial article 400 made from the above steps, having adhesive 401 on body-contacting surfaces of the web base sections 204, proximal section 403, distal section 404, anterior end 405, and posterior end 406.

The absorbent web used in the method as described above in Figures 17a-17f can be a single layer or multiple layers comprising suitable absorbent material as disclosed in the forthcoming sections of the specification. Likewise, the liquid impermeable material can be constructed with a number of materials and in a number of configurations, all of which are expanded upon below.

Figures 18a and 18b depict a second method of making a body-adhering absorbent interlabial article as provided by the present invention. Figure 18a shows a section of an absorbent web 200, with optional fluid permeable cover material 201, and optional adhesive means 202 to provide stability to a web projection formed by folding the web on itself. The web is folded on itself along the web central axis D-D, as shown in Figure 18a, to form a web folded edge and juxtaposed web sections. A liquid impermeable

material is then wrapped around the juxtaposed web sections, totally encasing the web sections. Adhesive is then applied to a part of the liquid impermeable material, on its outward surface. Figure 18b illustrates a finished body-adhering absorbent interlabial article 500 made from the above steps, having adhesive 401 on the liquid impermeable material 300.

The adhesive choice for embodiments of this invention depends on the nature, condition and sensitivity of the anatomical surface to which the article is to be adhered. For example, the composition and properties of adhesives that adhere to predominantly hair-containing surfaces may be different from those that adhere to relatively hairless surfaces.

Additionally, adhesives that are meant to adhere to sensitive areas such as the interlabial surfaces (associated with the labia minora and labia majora), the vestibule and to relatively less hairy internal surfaces of the vulva, will have different requirements by being more sensitive to pressure, rubbing and chafing, as well as often being moist. Those skilled in the art would readily appreciate that more than one type of adhesive, and combinations or mixtures of these adhesives, can suitably be used on the articles of the present invention.

Preferred adhesives and their formulations are those that have no or relatively low irritation potential and no sensitization potential. So called "hypoallergenic" adhesives are preferred for having little or no potentially irritating components such as certain monomers, low molecular weight components and additives such as some antioxidants, plasticizers and stabilizers.

Multiple classes of adhesives are useful in the present invention, including but not limited to solution adhesives emulsion adhesives, warm melt adhesives, and hot melt adhesives. The adhesives can be either hydrophilic or hydrophobic. A representative, non-limiting list of adhesives includes adhesives based on the following: emulsion or solvent-borne adhesives of natural or synthetic polyisoprene, styrene-butadiene, or polyacrylate, vinyl acetate copolymer or combinations thereof; hot melt adhesives based on suitable block copolymers - suitable block copolymers for use in the invention include linear or radial co-polymer structures having the formula $(A-B)_x$ wherein block A is a polyvinylarene block, block B is a poly(monoalkenyl) block, x denotes the number of polymeric arms, and wherein x is an integer greater than or equal to one; and hot melt adhesive based on olefin polymers and copolymers wherein the olefin polymer is a

terpolymer of ethylene and a co-monomer, such as vinyl acetate, acrylic acid, methacrylic acid, ethyl acrylate, methyl acrylate, n-butyl acrylate vinyl silane or maleic anhydride.

Suitable block A polyvinylarenes include, but are not limited to polystyrene, polyalpha-methylstyrene, polyvinyltoluene, and combinations thereof. Suitable block B
5 poly(monoalkenyl) blocks include, but are not limited to conjugated diene elastomers, such as for example polybutadiene or polyisoprene or hydrogenated elastomers, such as ethylene butylene or ethylene propylene or polyisobutylene, or combinations thereof. Commercial examples of block copolymers include KRATON brand elastomers from Shell Chemical Company, VECTOR brand elastomers from Dexco, SOLPRENE brand
10 elastomers from Enichem, and STEREON brand elastomers from Firestone Tire & Rubber Co. Commercial examples of olefin polymers and copolymers include ATEVA brand polymers from AT plastics, NUCREL brand polymers from DuPont, and ESCOR brand polymers from Exxon Chemical.

Additional adhesives useful in the present invention are polysiloxane adhesives,
15 described in US 5,618,281; pressure sensitive adhesives that are used to adhere ostomy appliances and certain wound care devices to the body, having formulations such as mixtures of gelatin, sodium carboxymethyl cellulose and polycarbons such as polyisobutylene, e.g., that described in US 4,795,449, and sold by Hollister, Inc. under the name of HOLLIHESIVE; hydrocolloids, containing, e.g., about 70% of a nitrile adhesive,
20 as well as VISTANEX, from Exxon Corp., and pectin; hydrophilic hydrogel adhesive materials, e.g., PROMEON sold by Promeon Division of Medtronic, Inc., as described in US 5,074,855; and poly 2-hydroxyethylmethyl methacrylate, plasticized with polyethylene glycol, other plasticizers being propylene glycol, polypropylene glycol, glycerin and water, as described in US 5,336,208.

25 The preferred gentle (atraumatic) adhesive formulations for the present invention are "gel-like" in nature, falling within these formulations are the hydrogel and oil block copolymer based adhesives, such as those disclosed in US Patent Numbers 4,833,193; 5,559,165; and 5,074,855. The lower modulus of these gel-like adhesives will allow them to undergo greater deformation. Thusly, they can more easily encapsulate pubic hair and
30 conform to the anatomical surfaces in the perineal region, assuring satisfactory bond strength when attached to the body. As shearing and bending forces are applied to the adhesive bond layer, during the wearing of the article, a sufficiently thick coating will allow deformation, thus limiting fracture forces that would lead the article's detachment. Upon removal, the lower adhesive strength of the adhesive gels, combined with the

lubricious nature of the high oil content, will allow these adhesive gels to be removed from the skin painlessly.

The coating thickness, tack, and peel force properties of adhesives are defined below to achieve the required balance required for adequate, but not aggressive, adhesive attachment and easy, painless and otherwise atraumatic removal and reapplication to the same anatomic areas. A range of coating weights useful in this invention is from about 1.5 to about 2,000 milligrams / square centimeter, with a preferred range of from about 190 about 1,600 milligrams / square centimeter, and a most preferred range of about 300 to about 1,100 milligrams / square centimeter.

Tack values of adhesives useful in the present invention, as measured according to the standardized test method ASTM D-2979, are preferably from about 100 to about 500 grams, more preferably from about 150 to about 300 grams, and most preferably from about 175 to 250 grams. The above tack values are based on an adhesive coating thickness as described heretofore.

Peel force values of adhesives useful in the present invention, as measured according to the standardized test method PSTC-1 180 degrees peel test (Pressure Sensitive Tape Council), are preferably less than about 325 grams / centimeter width, more preferably less than about 150 grams / centimeter width, and most preferably less than about 100 grams / centimeter width.

Techniques used for applying the adhesives to the article include, but are not limited to slot coating, spraying, knife coating, extrusion coating, and transfer coating, such as screen by screen and gravure. The adhesives may also be foamed prior to application, such as by using commercially available equipment from the Nordson Corporation.

Adhesives may be coated in continuous or in discrete patterns from emulsion or solution directly onto the product substrate or onto a release substrate to be subsequently transferred onto the article. If the adhesive is coated onto an article region that is meant to accept and absorb liquid, then it is preferred that the adhesive be applied as a discontinuous or fiberized coating or porous film, thereby creating voids; or that a continuous adhesive coating be hydrophilic and water penetrable by virtue of having a hydrophilic component polymer of the adhesive or suitable hydrophilic additive.

The absorbent material useful in the present invention may comprise either simple or complex absorbent structures that accept, transfer, distribute, store and retain fluid as well as prevent fluid from exiting the absorbent product. The absorbent material may be

composed of one or more layers of like, or dislike elemental features. The absorbent material may be a simple absorbent such as woodpulp, which may contain stabilizing components such as synthetic fibers that are used as such to form a bridging matrix; or by being thermobondable and fused to themselves and to the woodpulp, to form a dimension
5 stabilizing structure.

The synthetic fibers may be either hydrophilic, such as rayon, or hydrophobic such as polypropylene and polyester. The synthetic fibers may be made more wettable by treatment with a wetting agent such as a surfactant, by caustic etching of fibers such as those made of polyester, by incorporating wettable polymers such as polyethylene oxide
10 or polyvinyl alcohol within the fiber polymer formulation, by grafting wettable reactants to the fiber surface and by exposing the fiber to corona discharge. The peripheral profile of synthetic fibers may be of any shape. The synthetic fibers may also contain grooves, channels or bores; and may be pitted or perforated. The absorbent material may also contain auxiliary absorbents such as rayon or cotton fibers, sphagnum moss and
15 superabsorbent fibers or particles. The amount of superabsorbent material contained by the article can range from about 0.1 grams to about 5 grams, more preferably from about 0.2 grams to about 2.5 grams, and most preferably from about 0.3 grams to about 1 grams.

Absorbents such as sphagnum moss, in board or in compressed layer form, may
20 additionally function as compression or deformation resisting structures or to help maintain the shape of the absorbent structure in production and in use. Absorbents in board form may be made flexible and conforming by tenderizing by means such as passing the board through corrugating, embossing or perforating processes. The woodpulp itself may also be at least in part comprised of any of wet crosslinked, dry
25 crosslinked, chemically stiffened or curly fibers. The synthetic fibers and auxiliary absorbents may be present homogeneously throughout the absorbent material, in discrete layers or in continuous or discontinuous concentration gradients. The absorbent material may also contain foam in the form of layers or particles, the foam being either hydrophobic or hydrophilic, depending on its place and function in the product, e.g.,
30 absorbing, cushioning, deformation resisting and compression resisting. The absorbent material may be uncompressed, compressed, or otherwise densified, at least in part. Compression and densification may be homogeneous throughout the absorbent material or in discrete layers or in continuous or discontinuous gradients of density.

A liquid permeable cover material may optionally be used to encase portions of the absorbent material. The liquid permeable material may be made of at least one layer of any perforate material penetrable by liquids, including woven or knitted, but more commonly nonwoven, fabrics, non reticulated open cell foam, perforate films or combinations thereof. The nonwoven fabrics include any of those made of staple fibers, continuous filaments, the staple fibers having included among them natural fibers such as cotton, jute, ramie, woodpulp and kenaf and the synthetic fibers having included among them, rayon, polyolefins such as polyethylene, polypropylene, polyesters, polyamides, polyacrylonitriles, polyvinyl esters and multicomponent fibers, the multicomponent fibers being made of a low melting polymer that is at least in part exposed on the fiber's surface, and a high melting polymer. The nonwoven fabrics may be created from the fibers and/or filaments by any of the known fabric forming processes, where applicable, such as: web consolidation and bonding processes, e.g., by wetlaying or drylaying to form a random web or by drylaying to be converted to a carded web, either web to be bonded with chemical binders or by thermal means such as through-air bonding; and by direct fabric forming, e.g., by hydroentangling, spunbonding or meltblowing.

The perforate films have perforations that may be of two or three dimensions in profile through the thickness of the film, the films being made of polymers that include polyethylenes, polypropylenes, polyurethanes, polyamides, copolymers of ethylene and vinyl acetate and the like and combinations thereof. If the fabrics or films are hydrophobic and need to be made wettable they may be made wettable, to varying degrees, e.g., by treating the film with a surfactant, by exposure to corona discharge, by grafting the film with wettable reactants, by caustic etching of films such as those made of polyester, and by incorporating wettable polymers such as polypropylene oxide and polyvinyl alcohol in the polymeric formulation used to make the fiber or film.

In an effort to improve the fluid management properties of the absorbent interlabial article, an optional transfer layer (acquisition layer) can be added, which is usually located between the absorbent material and the liquid permeable cover material. However, the transfer layer may be located elsewhere, e.g., within or below the absorbent material. Transfer layers can provide many functions, including but not limited to, wicking fluid to available absorbent material, acting as a one-way valve to prevent captured fluid from squeezing out, and providing resiliency to the article to prevent it from collapsing, especially when occupied with fluids.

Materials useful in transfer layers by be comprised of relatively less hydrophilic materials and structures, than is contained in the absorbent material, such as webs of meltblown polypropylene or polyester fibers. Such webs may also contain woodpulp entrained within. The transfer layer may also be comprised of low density, highloft
5 nonwoven webs comprised of woodpulp and synthetic fibers such as polyethylene, polypropylene, polyester, polyacrylonitrile and polyamide and multicomponent fibers described above. Such highloft webs may be bonded with chemical binders or by thermal means such as through-air bonding and thermal embossing. Transfer layer may also be comprised of a perforate film, whose profile through the thickness of the film is either
10 two-dimensional or preferably three-dimensional.

Multiple transfer layers may also be employed, as a means for improving the article's ability to manage fluid and for providing structurally stability. US Patent Number 5,752,945 ('945) discloses an absorbent article having a transfer sheet, wherein the transfer sheet has at least two layers. Patent '945 discloses that a first layer can
15 provide wet and dry resilience and liquid holding capacity, while the second layer can provide lateral wicking or flow paths in order to more uniformly distribute liquid across an absorbent core.

The interlabial article may comprise additional materials to encase portions of the absorbent material. In particular, the distal section of the article can contain a liquid
20 impermeable material as a backsheet, to help prevent the captured fluid from transferring to a user's body or clothing. The liquid impermeable backsheet may also contain portions of adhesive on its outwardly disposed surface, whereby a user can optionally attach the article to their undergarments.

The liquid impermeable backsheet can be of any flexible material that prevents the transfer through it of liquid but does not necessarily prevent the passages of gases.
25 Commonly used materials are polyethylene or polypropylene films.

Other materials that may be used as the liquid impermeable backsheets are made from those selected from films of polyesters, polyamides, ethylene vinyl acetate, polyvinyl chloride, polyvinylidene chloride, cellophane, nitrocellulose and cellulose
30 acetate. Coextruded and laminated combinations of the foregoing, wherein such combinations are permitted by the chemical and physical properties of the film, may be used. Liquid impermeable reticulated foams and repellent treated papers may also be used.

Films that are barriers to liquids, but permit gases to transpire, i.e., "breathable barriers", may be used. These may be selected from polyurethane films and from microporous films in which microporosity is created by ionizing radiation or by leaching out of soluble inclusions using aqueous or nonaqueous solvents. Single or multiple layers of permeable films, fabrics and combinations thereof, that provide a tortuous path, and/or whose surface characteristics provide a liquid repellent surface to the penetration of liquids may also be used to provide such breathable barriers.

There are a number of techniques useful to assembly all or the above mentioned elements into the final article, including but not limited to by heat sealing, by use of hook and fastener technology, by use of construction adhesives, by use of ultrasonics, Preferably, construction adhesives are used in adhering the elements together. A representative, non-limiting list of materials useful as the construction adhesive includes acrylics; starch based hot melts; adhesives based on block copolymers of vinyl aromatic hydrocarbon and one or more conjugated diene or hydrogenated aliphatic blocks; polylactic acids; hot melts based on polyolefins such as amorphous polyalphaolefins which may consist of one or more of the following monomers: propylene, ethylene, butane, and hexene; hot melts based on low density polyethylene or low density polyethylene copolymers including ethylene vinyl acetate, methyl acrylate, n-butyl acrylate, and acrylic acid.

The entire absorbent interlabial article may be made of simple combinations or composites of materials that provide both liquid absorbency and liquid impermeability.

The disclosures of all patents, as well as any corresponding published foreign patent applications, mentioned throughout this patent application are hereby incorporated by reference herein. It is expressly not admitted, however, that any of the documents incorporated by reference herein teach or disclose the present invention.

While particular embodiments of the present invention have been illustrated and described, other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

What is claimed is:

1. An absorbent article sized and configured to fit predominantly between a user's labia,
5 comprising: an absorbent structure, having a proximal part and a distal part,
comprising body-facing and opposite-facing outwardly disposed surfaces
respectively; and adhesive located on at least a portion of the body-facing outwardly
disposed surface, for releasably attaching the article to the user's body.
- 10 2. The article as recited in Claim 1 wherein the opposite-facing outwardly disposed
surface comprises a liquid impermeable backsheet.
3. The article as recited in Claim 2 wherein the liquid impermeable backsheet is gas
permeable.
- 15 4. The article as recited in Claim 1 wherein the body-facing outwardly disposed surface
comprises a liquid permeable cover.
5. The article as recited in Claim 1 wherein a coating weight of the adhesive is from
20 about 1.5 to about 2,000 milligrams / centimeter.
6. The article as recited in Claim 1 wherein the adhesive is selected from the group
consisting of solution adhesives, emulsion adhesives, warm melt adhesives, hot melt
adhesives and foamed adhesives.
- 25 7. The article as recited in Claim 1 wherein the adhesive is hydrophilic.
8. A method for making an absorbent article sized and configured to fit predominantly
between a user's labia, comprising the following steps:
30 a) providing a web of absorbent material, having a central longitudinal axis;
b) covering at least part of said web with a liquid permeable material;
c) folding the web on itself along its central longitudinal axis, thereby forming a
folded edge and juxtaposed sections;

- d) folding the juxtaposed sections of the web outward from and coplanar with each other, along a line distal to said folded edge, thereby forming a web structure having a projection and base sections, wherein the distance between the line and the folded edge defines a projection height;
- 5 e) providing a liquid impermeable material, having a central longitudinal axis;
- f) folding the liquid impermeable material on itself along its central longitudinal axis, thereby forming a folded edge and juxtaposed sections;
- g) folding the juxtaposed sections of the liquid impermeable material outward from and coplanar with each other along a line distal to said folded edge, thereby
- 10 forming a liquid impermeable structure having a projection and base sections, wherein the distance between the fold line and the folded edge defines a projection height;
- h) aligning and attaching the web base sections to the liquid impermeable base sections, wherein the web projection and the liquid impermeable projection are
- 15 outwardly disposed in opposite directions, thereby forming a absorbent structure; and
- i) separating the absorbent structure into a plurality of absorbent interlabial articles.
9. The method as recited in Claim 8 further comprising the step of applying an adhesive
- 20 to at least a portion of an outwardly disposed surface of the web base sections.
10. The method as recited in Claim 85 further comprising the step of applying an adhesive to at least a portion of an outwardly disposed surface of the web projection.

25

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FIG. 7

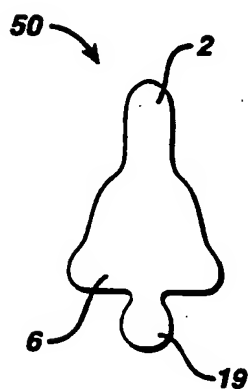


FIG. 8

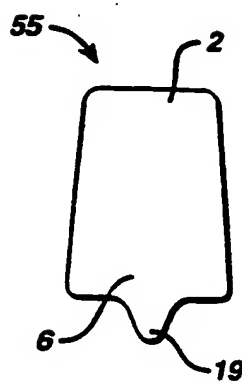


FIG. 9

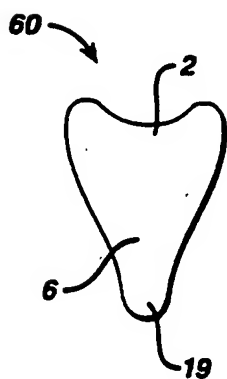
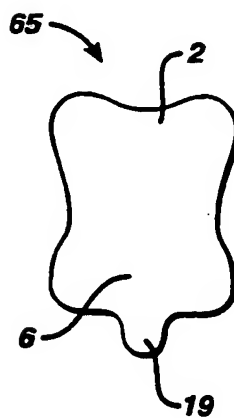


FIG. 10



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FIG. 11

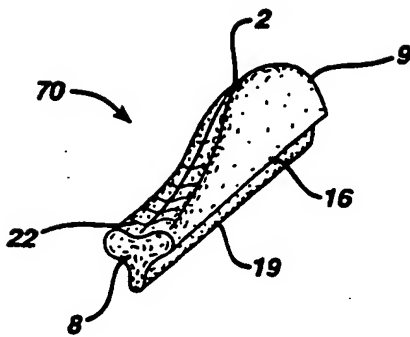


FIG. 12

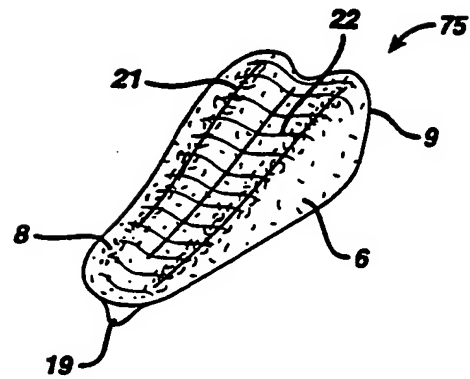


FIG. 13

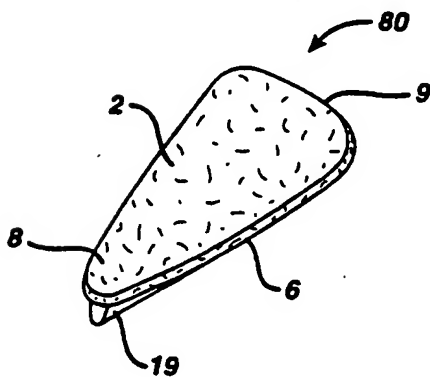
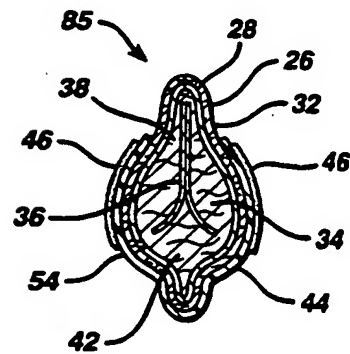


FIG. 14



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FIG. 15

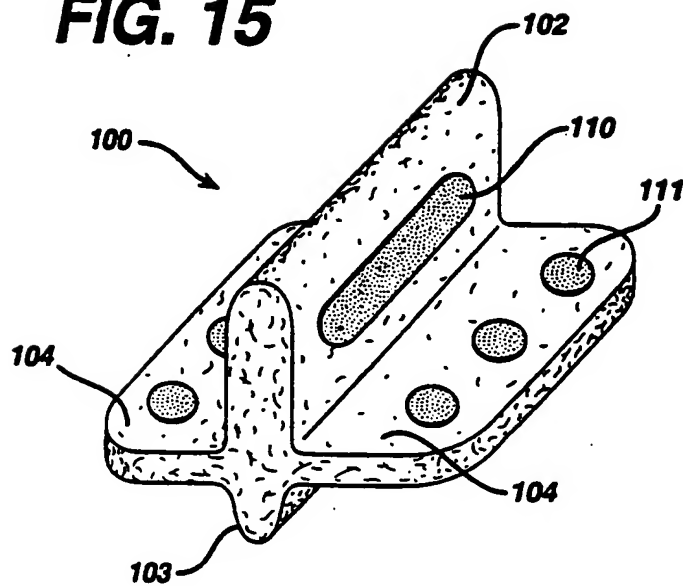
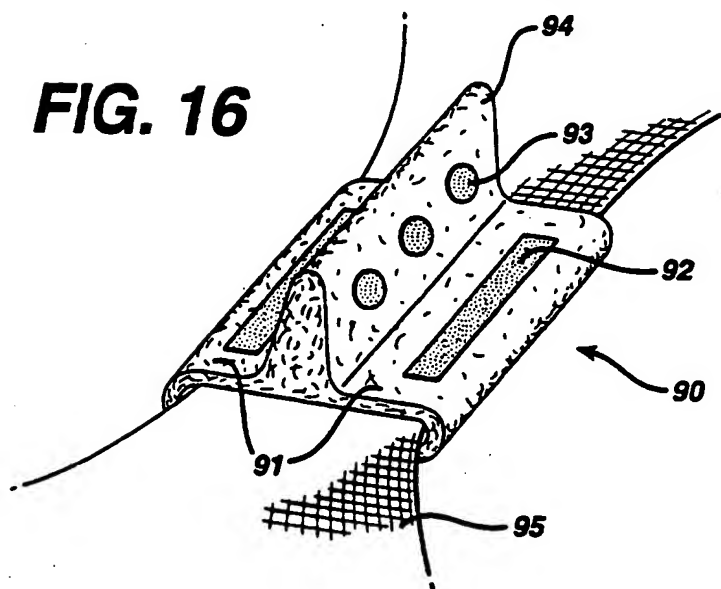


FIG. 16



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FIG. 17a

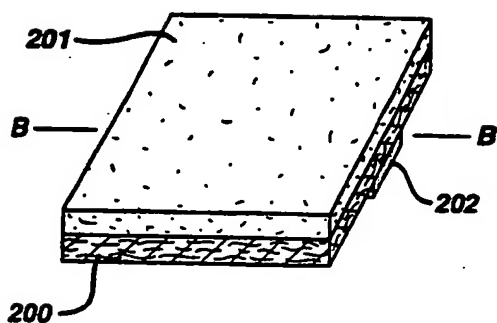


FIG. 17b

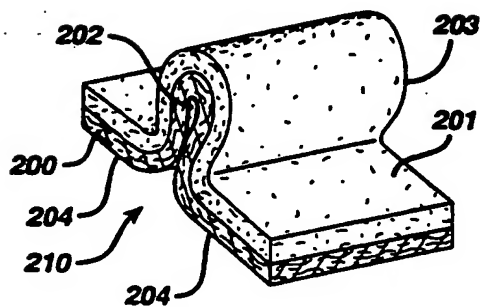


FIG. 17c

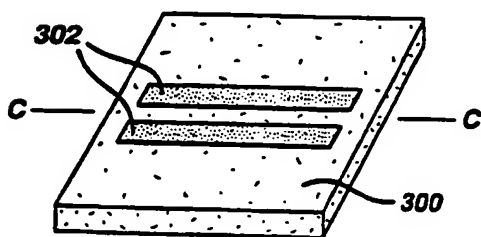


FIG. 17d

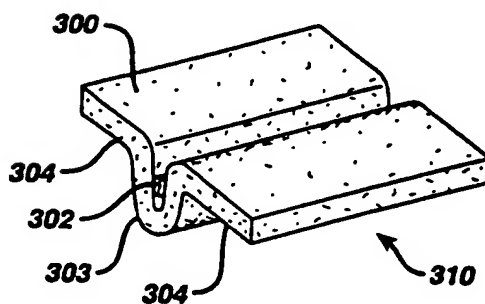


FIG. 17e

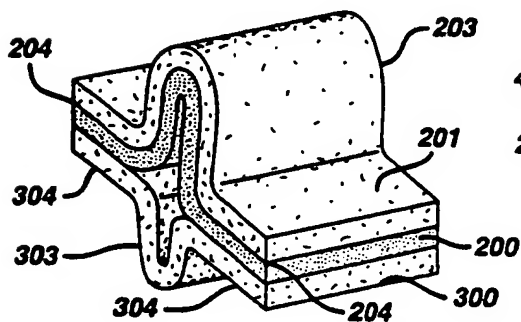
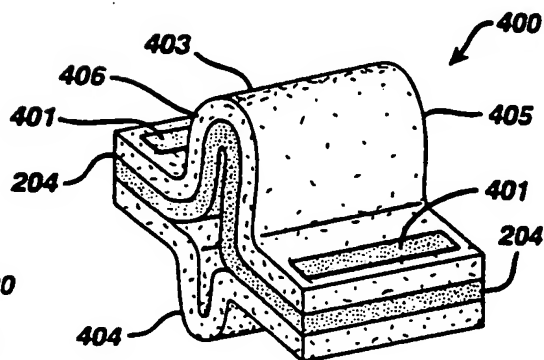


FIG. 17f



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FIG. 18a

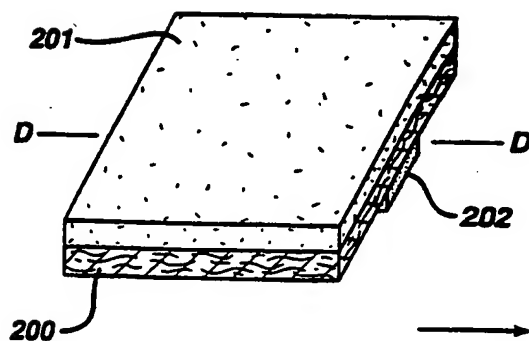
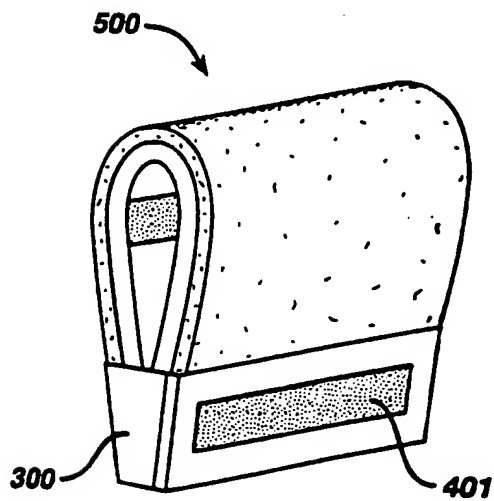


FIG. 18b



INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 99/29174

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F13/20 A61F13/82

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 850 628 A (PROCTER & GAMBLE) 1 July 1998 (1998-07-01) abstract column 17, line 58 - column 18, line 2 column 18, line 19 - line 23 column 21, line 8 - line 14; figures 1, 5A-C	1-4, 7-10
A	US 5 336 208 A (ROSENBLUTH ROBERT F ET AL) 9 August 1994 (1994-08-09) abstract; figures 1, 8, 9	1-10
A	US 5 769 091 A (MCLAUGHLIN PAUL D ET AL) 23 June 1998 (1998-06-23) abstract column 6, line 45 - line 64; figures 6D, 6E	1-10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

30 May 2000

Date of mailing of the international search report

14/06/2000

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Westermayer, W

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/29174

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0850628 A	01-07-1998	EP 0850619 A	01-07-1998
		AU 7784998 A	25-01-1999
		EP 0993288 A	19-04-2000
		WO 9901094 A	14-01-1999
		AU 5385398 A	17-07-1998
		AU 5531598 A	17-07-1998
		AU 5612598 A	17-07-1998
		AU 5612698 A	17-07-1998
		AU 5612998 A	17-07-1998
		AU 5619598 A	17-07-1998
		AU 5619698 A	17-07-1998
		AU 5619798 A	17-07-1998
		AU 5708898 A	17-07-1998
		AU 5709198 A	17-07-1998
		AU 5709498 A	17-07-1998
		AU 5801498 A	17-07-1998
		AU 5801598 A	17-07-1998
		CN 1246060 A	01-03-2000
		CN 1246061 A	01-03-2000
		CN 1246062 A	01-03-2000
		CN 1246044 A	01-03-2000
		CN 1246063 A	01-03-2000
		CN 1246064 A	01-03-2000
		CN 1246065 A	01-03-2000
		CN 1246066 A	01-03-2000
		CN 1246067 A	01-03-2000
		CN 1246068 A	01-03-2000
		EP 0850624 A	01-07-1998
		EP 0853934 A	22-07-1998
		EP 0852149 A	08-07-1998
		EP 0850649 A	01-07-1998
		EP 0855190 A	29-07-1998
		EP 0948364 A	13-10-1999
		EP 0957871 A	24-11-1999
		EP 0948365 A	13-10-1999
		EP 0968007 A	05-01-2000
		EP 0946213 A	06-10-1999
		EP 0946214 A	06-10-1999
		EP 0946215 A	06-10-1999
		EP 0948366 A	13-10-1999
		EP 0948367 A	13-10-1999
		EP 0948368 A	13-10-1999
		EP 0948369 A	13-10-1999
		NO 993054 A	23-08-1999
		NO 993060 A	23-08-1999
		WO 9827909 A	02-07-1998
		WO 9828014 A	02-07-1998
		WO 9828015 A	02-07-1998
		WO 9827914 A	02-07-1998
		WO 9828016 A	02-07-1998
US 5336208 A	09-08-1994	US 5074855 A	24-12-1991
		AT 182772 T	15-08-1999
		CA 2100090 A	11-07-1992
		DE 69229719 D	09-09-1999
		DE 69229719 T	23-12-1999
		EP 0566687 A	27-10-1993
		ES 2137181 T	16-12-1999

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 99/29174

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5336208 A		GR 3031353 T	31-01-2000
		JP 6506368 T	21-07-1994
		WO 9211825 A	23-07-1992
		US 5927282 A	27-07-1999
US 5769091 A	23-06-1998	US 5509427 A	23-04-1996
		AU 1808597 A	28-08-1997
		WO 9728767 A	14-08-1997
		AU 7731294 A	18-04-1995
		BR 9407593 A	07-01-1997
		CA 2172136 A	06-04-1995
		CN 1131385 A	18-09-1996
		EP 0720460 A	10-07-1996
		FI 961253 A	09-05-1996
		JP 9502908 T	25-03-1997
		NO 961118 A	13-05-1996
		WO 9508968 A	06-04-1995
		US 5724994 A	10-03-1998
		US 5752525 A	19-05-1998